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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,399	04/03/2006	Jurgen Dorn	568-PDD-03-08-US-[13P]	9700
34284	7590	04/02/2010		
Rutan & Tucker, LLP. 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626			EXAMINER EVERAGE, KEVIN D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 04/02/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,399	Applicant(s) DORN ET AL.	
	Examiner KEVIN EVERAGE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5,6 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-10,12-14 and 16-29 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed January 8, 2010 is fully considered. Claim 11 is cancelled. Claim 30 is new. Claims 1-10 and 12-30 are pending. Claims 2, 3, 5, 6 and 15 are withdrawn from consideration. Claim 1 has been amended to incorporate subject matter from cancelled claim 11.

Claim Objections

2. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1, 4, 7-10, 13, 14, 16, 18, 21, 23, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorn et al. (US 2002/0183826 A1) in view of Vale et al. (US 2002/0058963 A1).**

Dorn et al. ("Dorn") discloses a retrieval catheter comprising:

a catheter wall (54) defining a catheter lumen and a distal tip that is tapered

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toward an open distal orifice (see Paragraph 75) defining a distal end of the catheter lumen the wall over the length of the tapered tip configured to distend to expand the distal orifice (see Paragraph 91);

a distender (56) disposed in the catheter lumen and configured to press radially outwardly the catheter wall at the distal tip to expand the distal orifice;

the distender having a distal end annulus and a proximal end annulus separated by a radially outward-facing circumferential wall and an axial lumen extending through the distender between said distal and proximal annuli (see Figures 2a-2d);

a pusher shaft (64) that extends proximally beyond a proximal end of the catheter lumen and that is configured to push the distender distally until the distal end annulus is distal of the catheter distal orifice and the open distal orifice of the catheter is distended (see Figures 5 and 6 for distension of catheter distal orifice caused by distal end annulus of distender);

wherein the catheter is configured as an over-the-wire catheter (see Paragraph 58);

including a guide catheter with a lumen to receive the retrieval catheter (see Paragraph 27);

wherein the guide catheter has a tapered distal end portion and the retrieval catheter is a snug fit with a distal end orifice of the tapered distal end portion of the guide catheter (see Paragraph 29);

wherein the distender comprises radiopaque material (60);

wherein the catheter wall includes an annular radiopaque marker adjacent the

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distal tip (80);

wherein the distender distal end annulus (76) exhibits an end face transverse to the axis of the lumen of the distender (see Figure 2c);

further comprising a device to be retrieved (152), the device including a pull line (150) having a length to extend from the device to at least the proximal end of the catheter lumen, the distender distal end annulus configured to receive at least a proximal portion of the device (see Paragraph 86);

wherein the device is a filter (see Figure 3J) for filtering passage of bodily fluid within a bodily lumen; and

wherein the catheter shaft includes a first opening (74) in a wall thereof positioned adjacent the distal tip and a second opening (67) in the catheter shaft wall spaced proximally from the first opening.

Dorn does not disclose a frusto-conical annular element co-axial with the annular distender ring, the annular element positioned proximal of the distender ring with its larger diameter end contiguous therewith. However Vale et al. ("Vale") discloses such an element that allows for a "smooth, step free crossing profile between the centering catheter distal end 50 and the retrieval catheter tip 19 in the advancement mode" (see Paragraph 85). Since the distender disclosed by Dorn extends past the catheter wall it would have been obvious to someone of ordinary skill in the art at the time of the invention to manufacture the Dorn distender's distal end in the claimed manner as disclosed by Vale to allow for the step free crossing profile during the advancement

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mode in light of Vale's disclosure.

5. Claims 17, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn et al. (US 2002/0183826 A1).

Dorn discloses the pusher shaft being a metal pusher rod (see Paragraph 72) bonded to the distender body (see Figure 2d) but does not disclose the pusher shaft comprising a stainless steel hypotube. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the pusher shaft to comprise a stainless steel hypotube, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Dorn discloses the pusher element being a rod but does not disclose the pusher element including a lumen, a proximal opening and a distal opening. It would have been an obvious matter of design choice to configure Dorn's pusher rod with the claimed configuration, since applicant has not disclosed that the lumen or openings solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with such common configuration.

Dorn discloses the catheter shaft having a guide catheter (see above) and an aspirating function through the first and second openings (see Paragraph 67) but does not disclose the catheter shaft disposed in a lumen of the guide catheter having an aspirating position wherein the first opening is distal to the guide catheter distal tip. However it would have been obvious to someone of ordinary skill in the art at the time of

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the invention to extend the catheter shaft past the distal end of the guide catheter distal tip at the treatment site (where the guide catheter has served its purpose) to perform the aspirating function, and the second opening would have likewise been proximal thereto in the guide catheter lumen.

6. Claims 1, 4, 7-10, 12-14, 16-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (US 2002/0058963) in view of Dorn et al. (US 20020183826).

Vale discloses a retrieval catheter comprising:

a catheter wall (10) defining a catheter lumen and a distal tip that is tapered toward an open distal orifice (71) defining a distal end of the catheter lumen the wall over the length of the tapered tip configured to distend to expand the distal orifice (see Paragraph 78);

a distender (11) disposed in the catheter lumen and configured to press radially outwardly the catheter wall at the distal tip to expand the distal orifice;

the distender having an annular distender ring and a frusto-conical annular element co-axial with said distender ring, the annular element positioned proximal of the distender ring with its larger diameter end contiguous therewith (see figure below), and an axial lumen extending through the distender between the annular distender ring and the frusto-conical annular element (see Figures 10-12);

wherein the device is configured as an over-the-wire (25) catheter (see Figure 10);

wherein the retrieval catheter includes a guide catheter (42) with a lumen to receive the retrieval catheter (see Paragraph 72);

wherein the distender ring comprises radiopaque material (see Paragraph 73);

wherein the annular distender ring exhibits an end face transverse to the axis of the lumen of the distender (see Figures 10-12);

further comprising a device (2) to be retrieved, the device including a pull line (25) having a length to extend from the device to at least the proximal end of the catheter lumen, the annular distender ring configured to receive at least a proximal portion of the device (see Figure 15);

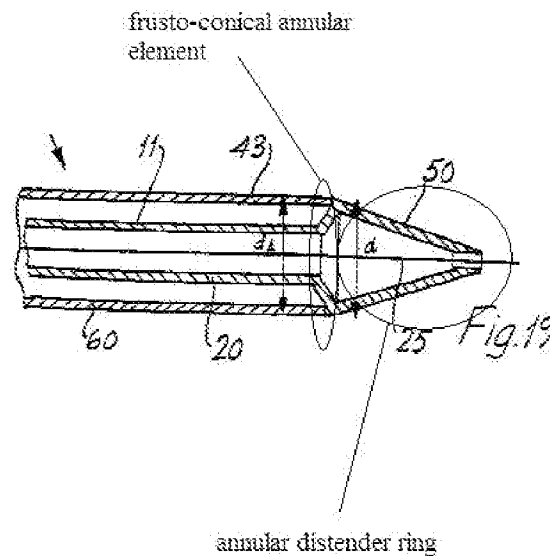
wherein the device is a filter for filtering passage of bodily fluid within a bodily lumen (see Paragraph 70);

wherein the distender includes a return cone positioned about an outer surface of the body proximal of the annular element, the return cone having a frusto-conical configuration with a large diameter end approximately equivalent to the outside diameter of the annular element, the large diameter end contiguous with the annular element (The figure below shows the large diameter end being approximately equivalent to the outside diameter of the annular element. Other embodiments, such as Fig. 15 of Vale show an equivalent diameter. It would have been obvious to someone of ordinary skill in the art at the time of the invention to set the diameters equivalent to each other for ease of transition as the distender is retracted back into the catheter lumen); and

wherein the annular element and return cone are bonded to the body by an

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adhesive. The claimed phrase "bonded to the body by an adhesive" is being treated as a product by process limitation; that is any process of bonding the annular element and return cone to each other creates the claimed apparatus. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The annular element and return cone disclosed by Vale are integrally bonded to one another.



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Vale does not disclose a pusher shaft that extends proximally beyond a proximal end of the catheter lumen and that is configured to push the distender distally until the distal end annulus is distal of the catheter distal orifice and the open distal orifice of the catheter is distended. However Dorn discloses a pusher shaft for a similarly functioning retrieval apparatus that allows the user to control the distender from a proximal handpiece (see Paragraph 72). It would have been obvious to someone of ordinary skill in the art at the time of the invention to equip the distender disclosed by Vale with pusher shaft as disclosed by Dorn, or more specifically a stainless steel hypotube which is commonly used in the art, for easier manipulation from a handpiece in light of Dorn's disclosure. Dorn discloses the pusher shaft being a metal pusher rod (see Paragraph 72) bonded to the distender body (see Figure 2d) but does not disclose the pusher shaft comprising a stainless steel hypotube. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the pusher shaft to comprise a stainless steel hypotube, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Dorn discloses the pusher element being a rod but does not disclose the pusher element including a lumen, a proximal opening and a distal opening. It would have been an obvious matter of design choice to configure Dorn's pusher rod with the claimed configuration, since applicant has not disclosed that the lumen or openings solve any stated problem or is for any particular purpose and it appears that the invention would perform equally well with such common configuration.

Regarding claim 8:

Vale discloses the distender being a snug fit with a distal end orifice of the retrieval catheter but does not disclose the guide catheter having a tapered distal end portion and the retrieval catheter being a snug fit with a distal end orifice of the tapered distal end portion of the guide catheter. However Vale discloses an embodiment of a guide catheter having a tapered distal end portion (see 71, Figure 6). It would have been obvious to someone of ordinary skill in the art at the time of the invention that the guide catheter could have a tapered distal end portion fitting snugly with the retrieval catheter in the manner demonstrated by Figure 6.

Regarding claim 10:

Vale does not disclose the catheter wall including an annular radiopaque marker adjacent the distal tip. However since Vale discloses the use of radiopaque markers with the distender it would have been obvious to someone of ordinary skill in the art at the time of the invention that an annular radiopaque marker adjacent the distal tip of the catheter wall would show how far the distender extends in relation to the catheter.

Response to Arguments

7. Applicant's arguments filed January 8, 2010 have been fully considered but they are not persuasive.

Applicant argues that Vale's distender does not comprise a ring. However the

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distal portion (50) of the distender is a round, open-ended tube constituting a ring.

Applicant argues that Dorn does not disclose the features of a tubular body and an annular element positioned about an outer surface of the body of the distender. The claim requires the distender having a distal end annulus and a proximal end annulus. Since an annulus is a ring portion any two ring portions of the distender 56 separated by a space of the tubular body constitute distal and proximal annulus of the distender.

In response to arguments related to claim 19, the return cone is disclosed by Vale as shown by the frusto-conical annular element in the figure above.

In response to arguments related to claim 29, the method steps are anticipated by Vale in the rejections above.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN EVERAGE whose telephone number is (571)270-7485. The examiner can normally be reached on 9-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN EVERAGE
Examiner
Art Unit 3734

/K.E./

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734